



Proposed Course Schedule

CTD / eCTD: Building the Marketing Application Throughout Clinical Development (Modules 1-5)

Note: Each session is 90 minutes in duration with time for Question-Answer period; 15-30 minutes break between sessions.

Day/Modules	Session
DAY 1 CTD Introduction Module 1 Regional Module 2 Quality Overall Summary Module 3 Quality	Session 1A: Overview of CTD, Module 1 Session 1B: Drug Substance Characterization and Impurities Session 1C: Manufacture of Drug Substance and Drug Product Session 1D: Pharmaceutical Development
DAY 2 Module 3 Quality Module 2 Nonclinical Overview and Summary Module 4 Nonclinical	Session 2A: Control of Drug Substance, Drug Product, Excipients, Container Closure Session 2B: Stability of Drug Substance and Drug Product, Appendices Session 2C: Nonclinical Overview and Module 4 Session 2D: Nonclinical Written and Tabulated Summaries
DAY 3 Module 1 Labeling Module 2 Clinical Overview Clinical Summary Module 5 Clinical	Session 3A: Clinical Labeling – Module 1, Clinical Overview – Module 2 Session 3B: Clinical Study Reports Session 3C: Module 5, Clinical Summary, Integrated Summary of Efficacy (ISE) Session 3D: The Integrated Summary of Safety (ISS)